



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0627]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0183. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions--(OMB Control Number 0910-0183)--Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner of FDA (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for profit institutions or groups.

Section 10.33 (21 CFR 10.33) issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the

Commissioner on a petition submitted under 21 CFR 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision involved. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting from the Commissioner a reconsideration of a matter.

Section 10.35 (21 CFR 10.35), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with §10.20, the Commissioner to stay the effective date of any administrative action.

Such a petition must do the following: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act sets forth the format and procedures by which an interested person may request, in accordance with §10.20, an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the Agency's formal position for matters of general applicability.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of September 7, 2011 (76 FR 55396), to which the Agency received one comment. However, this comment did not address the information collection.

FDA estimates the burden of this collection of information as follows:

Table 1.-- Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.30	207	1	207	24	4,968
10.33	4	1	4	10	40
10.35	5	1	5	10	50
10.85	4	1	4	16	64
Total					5,122

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years. In 2010, FDA received approximately 207 petitions (§ 10.30), 4 administrative reconsiderations of action (§ 10.33), 5 administrative stays of action (§ 10.35), and 4 advisory opinions (§ 10.85).

Dated: March 12, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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